DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: JUN 21 2005

From: Consumer Safety Officer, Division of Dietary Supplement Programs , Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

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Subject of the Notification: _Sang-Hwang Mushroom_____

Firm: Herbal Cure USA LLC

Date Received by FDA: ___3/23/05_____

90-Day Date: ____6/21/05_____

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

___*Victoria Lutwak*___

19955-0316

RPT 279

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

Young H. Lee
Herbal Cure USA LLC
1165 Hillcrest Glenn Circle
Sugar Hill, Georgia 30518

JUN 8 2005

Dear Mr. Lee:

This is to inform you that the notification, dated March 16, 2005, you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on March 23, 2005. Your notification concerns the substance called "Sang-Hwang Mushroom," *Phellinus linteus* (Berk.& Curtis.) Teng, that you intend to market as a new dietary ingredient.

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

Federal regulations found at 21 CFR 190.6 specify the requirements for a pre-market notification for a new dietary ingredient. Your notification concerning "Sang-Hwang Mushroom" does not comply with the requirements of 21 CFR 190.6 and is incomplete. The following items were not included with your submission: (1) An original and two copies of the notification, (2) a description of the dietary supplement or dietary supplements that contains your new dietary ingredient, (3) the level of the dietary ingredient in the dietary supplement and (4) the conditions of use recommended or suggested in the labeling of the dietary supplement.

According to your notification, the "[l]evel of the new dietary ingredient in the product: 500 gram bag for three months use in making [the] tea." This appears to describe the total contents of the bag and not the level of the new dietary ingredient in the dietary supplement. The following information appears in the directions for use and contains the servings and serving levels and dosage form(s): "Sang-Hwang Mushroom" is prepared and used as follows: Directions: "Break the mushroom as small as a peanut size. Put 10 grams of mushroom and 2,000 cc water in a glass pot without cover and boil it with high heat (as long as the water would not run over) until it reduces about 1,000 cc which is 2 days portion. Pour it into the glass bottle, keep it in the refrigerator, and drink it one small cup (250 cc) in the morning and evening." However it is unclear whether it is the mushroom itself or the mushroom powder that is to be boiled in water and reduced since the powder is illustrated in the preparation section of your notification.

Your notification provided only citations and abstracts of the references that you relied on as evidence of safety. Any references to published information offered in support of the notification shall be accompanied by reprints or photostatic copies of such references. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. In addition, your notification did not include documented history of use of your new dietary ingredient as an article present in the food supply or as an article used for food in a form in which the food has not been chemically altered.

Your notification provides some history of use for "Sang-Hwang Mushroom" as a traditional Chinese medicine but does not provide documented evidence of "Sang-Hwang Mushroom" used as an ingredient in a dietary supplement. Thus, FDA cannot make an evaluation of the safety of "Sang-Hwang Mushroom" based on the history of use information provided in your notification.

Finally, your notification contains an acute oral toxicity study in rats using a brown powder called "Natural Sanghwang Mushroom." It is not evident that the test material used in the acute oral toxicity study in rats is the same as your new dietary ingredient. Therefore, it is uncertain how this study relates to evaluating the safety of the dietary ingredient "Sang-Hwang Mushroom Powder."

FDA is unable to determine whether the scientific studies cited in your notice provide an adequate basis for a conclusion that the dietary supplement will reasonably be expected to be safe because the information contained in your notice is incomplete. If you market your product without submitting a notification that meets the requirements of 21 CFR 190.6 (http://www.cfsan.fda.gov/~lrd/cfr190-6.html), or market your product less than 75 days after submitting such a notification, your product is considered adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of March 23, 2005. After the 90-day date, the notification will be placed on public display at FDA's Division of Dockets Management in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Linda S. Pellicore, Ph.D., at (301) 436-2375.

Sincerely yours,

Linda S. Pellicore

for Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition